

# EXHIBIT 3

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA

3 In re: Bair Hugger Forced Air  
4 Warming Products Liability  
5 Litigation

MDL No. 2666

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8 VIDEOTAPED DEPOSITION OF  
9 YADIN DAVID, Ed.D., P.E., C.C.E.  
10 Houston, Texas  
11 Tuesday, August 1, 2017  
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19 Reported by:

20 SUSAN PERRY MILLER, RDR, CRR, CRC

21 JOB NO. 124787  
22  
23  
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25

1 August 1, 2017

2 9:16 a.m.

3  
4 VIDEOTAPED DEPOSITION of YADIN DAVID,  
5 Ed.D., P.E., C.C.E., held at the offices of  
6 Thompson Coe LLP, One Riverway, Suite 1400,  
7 Houston, Texas, pursuant to Subpoena and the  
8 Federal Rules of Civil Procedure, before Susan  
9 Perry Miller, Registered Diplomate Reporter,  
10 Certified Realtime Reporter, Certified  
11 Realtime Captioner, and Notary Public in and  
12 for the State of Texas.  
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1 Y. DAVID

2 specifically was to see device operation and  
3 the inside of the device after it was used in  
4 the field. So on purposely, I wanted to get a  
5 device that had some field experience with it.

6 Q. Why?

7 A. Because it gives me a view of what  
8 the device's capability to sustain its  
9 features in the field after it's been used for  
10 a period of hours. For example -- and I  
11 pointed that in my report -- is that I looked  
12 at the four feet on the bottom of the device  
13 and gave -- and realized that this device was  
14 used much on the floor because you could see  
15 the wear and tear on those four points at the  
16 base of the device.

17 So a device sitting on the floor  
18 has different performance on its enclosure  
19 than a device that would be up on the shelf or  
20 on an IV pole.

21 Q. What do you mean, it has a  
22 difference in the enclosure?

23 A. The performance of the  
24 characteristics of the physical enclosure, the  
25 box that covered the whole internal operation

1 Y. DAVID

2 Do you believe that the operation  
3 of the Bair Hugger device you examined  
4 resulted in any difference in the inside of  
5 the compartment than would have occurred if  
6 the device had been operated in a different  
7 manner?

8 MR. BANKSTON: Object to the form.  
9 Object to the preamble.

10 A. I need to very simply clarify the  
11 purpose of my examination of the device. I  
12 wanted to see how the device is built, how  
13 it's put together, where the components  
14 physically sit, where is the intake, where is  
15 the output, how you connect the blanket to it,  
16 and I did not seek to make any performance  
17 comparison or derive any clinical outcome of  
18 the device use.

19 BY MS. EATON:

20 Q. When I asked you why you wanted a  
21 used device, you said you preferred one so  
22 that you could see its characteristics after  
23 use. Now that you describe the purpose here,  
24 let me ask a different question.

25 Would a new device have provided

1 Y. DAVID

2 Does that business involve any work  
3 other than litigation consulting?

4 A. Yes.

5 Q. What else do you do?

6 A. I provide biomedical engineering  
7 services to healthcare providers, meaning to  
8 hospitals that would like to improve their  
9 medical technology management program. I  
10 provide professional services to manufacturers  
11 of medical devices that would like to start or  
12 improve their field biomedical services.

13 Q. Field?

14 A. Correct.

15 Q. Do you mean servicing devices in  
16 the field?

17 A. Correct.

18 Q. Okay.

19 A. I provide regulatory services to  
20 startup companies in the medical device field.

21 Q. What does that mean, "regulatory  
22 services"?

23 A. Advise them on how to be ready for  
24 510(k) submission and the appropriate  
25 information to be included in such. And

1 Y. DAVID

2 finally, I am -- develop and implement  
3 telemedicine programs.

4 Q. For the regulatory advice that you  
5 provide, is it advice about the -- I would  
6 like more detail about that. What aspect of a  
7 510(k) submission is it that you're advising  
8 people about?

9 A. Sure. I'll be happy to help you  
10 with that. The 510(k) submission has a  
11 process that is looking for how to classify  
12 the device, how to identify a predicate  
13 device, what is the substantial equivalency  
14 criteria that one can use, and specifically to  
15 include studies and testing in a way that  
16 supports the submission.

17 Q. What training or education did you  
18 have that allows you to do that work, or that  
19 you draw upon when you do that work?

20 A. Sure. I've been working in the  
21 biomedical devices field for four decades and  
22 use my expertise to understand how a device  
23 works safely and what risk is associated with  
24 them, seeing it from the clinical side.

25 I have obtained education and

1 Y. DAVID

2 training throughout my career and have been  
3 working with a consultant to the Food and Drug  
4 Administration on several panels and have been  
5 trained by the Food and Drug Administration to  
6 fulfill that role. And I recently have been  
7 asked to become a regulatory advisor to the  
8 Innovation Institute of the Texas Medical  
9 Center based on my experience and training.

10 Q. What regulatory training -- you  
11 mentioned training, I think, regulatory  
12 training. What regulatory training have you  
13 had? Has it been part of any formal program  
14 that you can identify?

15 A. At the master level when I was at  
16 the university pursuing my degree, I took a  
17 regulatory course that was taught by a  
18 biomedical engineering professor. I continued  
19 at the doctorate level to obtain training in  
20 the field. I think it was a nurse who taught  
21 the course at the doctorate level, but  
22 regulatory principles. And I continuously  
23 attend the annual meeting of biomedical  
24 product and instrumentation and take a seminar  
25 and lectures as well as reading books that are

1 Y. DAVID

2 published as well as contributing to  
3 regulatory books myself. So I'm doing  
4 research to write my chapter for that.

5 Q. Okay. That's something ongoing  
6 right now?

7 A. No. That has been submitted,  
8 complete. The book has been published, I  
9 think end of last year.

10 Q. Is that on your CV?

11 A. Yes.

12 Q. Can you show me which one you're  
13 referring to? If you know the title off the  
14 top of your head, you can just tell me.

15 (Document review by witness.)

16 A. It looks like we don't have the  
17 recent year here on the copy I'm holding.

18 BY MS. EATON:

19 Q. Do you know the title of the book?

20 A. No.

21 Q. Are you able to provide me with an  
22 updated CV?

23 A. Sure.

24 Q. What was your chapter about?

25 A. I don't remember the title. It was

1 Y. DAVID  
2 about risk processes of medical devices  
3 subject to regulation.

4 Q. Of the regulation? What  
5 regulation?

6 A. Global medical device regulations.  
7 FDA, EU, others.

8 MR. BANKSTON: Is now a good time  
9 for a bathroom break? Should we do  
10 that?

11 MS. EATON: Sure.

12 THE VIDEOGRAPHER: We are going off  
13 the record at 10:42.

14 (Recess, 10:42 a.m. to 10:57 a.m.)

15 THE VIDEOGRAPHER: We are back on  
16 the record at 10:57.

17 BY MS. EATON:

18 Q. Dr. David, how many times have you  
19 met with attorneys that you understand to  
20 represent the plaintiffs in this Bair Hugger  
21 litigation, in person?

22 A. I don't keep count. Whatever is in  
23 my invoices, that would reflect it.

24 MS. EATON: And to be clear, I was  
25 hoping to get the remaining invoice

1 Y. DAVID

2 training, I went to seminars. I educated  
3 myself as to what the standard's purpose and  
4 what the principle of the categories that it  
5 addresses, and how one will use it as contrast  
6 with other risk assessment programs.

7 Q. What is ISO 14971? What is it  
8 intended -- what is it? What does it apply  
9 to?

10 A. It's basically quality system  
11 organization.

12 Q. I'm sorry. ISO Standard  
13 specifically 14971, do you know what that  
14 addresses?

15 A. It's addressed risk management.

16 Q. For what?

17 A. For medical devices.

18 Q. Did you consult that in connection  
19 with your work in this case?

20 A. No, I don't believe so.

21 Q. You are aware of it?

22 A. I am.

23 Q. You're aware that the risk in that  
24 standard is evaluated in connection with  
25 benefit?

1 Y. DAVID

2 A. That is correct.

3 Q. Have you ever worked within the  
4 Office of Compliance?

5 A. I did not.

6 Q. Have you ever taken part in  
7 reviewing a 510(k) application for clearance?

8 A. Yes.

9 Q. On behalf of the FDA?

10 A. Yes.

11 Q. In what context?

12 A. As a member of the advisory panel.

13 Q. Okay. When did you do that work?

14 A. It's a public record when the panel  
15 is called to admitting. You can find them  
16 online. I don't recall when it was done.

17 Q. Was it once or more than once?

18 A. More than once.

19 Q. How many devices -- you're saying  
20 as part of your work on the panel, you've  
21 reviewed a 510(k) application?

22 A. Yes.

23 Q. Okay. For how many devices?

24 A. I don't know, four, five.

25 Q. Do you recall what the devices are?

1 Y. DAVID

2 questions the panel was being asked at the  
3 times that you met?

4 A. The specific question? No, I don't  
5 remember.

6 Q. Do you remember the scope of the  
7 review you were asked to make?

8 A. The scope of the review was to  
9 determine if the instructions for use are  
10 sufficiently covering the risk associated with  
11 the use.

12 Q. In all of the cases that you  
13 recall, that was your scope?

14 A. In all the cases?

15 Q. I'm sorry. I believe I heard you  
16 say you thought -- I should -- I should say  
17 that differently.

18 You said you recalled that you  
19 reviewed perhaps four or five devices. Did  
20 that occur in one panel meeting or over  
21 several panel meetings?

22 A. Over several.

23 Q. In each situation where you were  
24 asked to review something for this panel that  
25 you've identified, was the scope of the review

1 Y. DAVID

2 to determine if IFUs sufficiently covered the  
3 risks?

4 A. No. There were additional charges  
5 for the panel. A second one was to determine  
6 if the submitter identified sufficient risk  
7 that might be existing in the clinical  
8 environment when the device is in use.

9 Q. Any other scope of review you could  
10 recall?

11 A. Is there sufficient -- if there is  
12 sufficient content in the classification of  
13 the device to ensure safety when this device  
14 is deployed, or there is a need for special  
15 control to be added.

16 Q. Do you recall what device that was?

17 A. That was some kind of injector.

18 Q. Injector?

19 A. Yes.

20 Q. Do you recall what kind of devices  
21 you reviewed IFUs for?

22 A. No.

23 Q. Any other scope of review you can  
24 recall?

25 A. There is another panel on the same

1 Y. DAVID

2 A. Biomedical engineering, trained and  
3 practice in the largest medical center in the  
4 country so I am bringing the engineering and  
5 the clinical exposure and appreciation for  
6 processes involve technology in patient care  
7 environment. It's a unique combination.

8 Q. Have you ever been involved in  
9 reviewing a question of whether a device was  
10 substantially equivalent to a predicate  
11 device?

12 A. During the panel convening that the  
13 question would come up, yes.

14 Q. You have a specific recollection  
15 that you've been asked to review that  
16 question?

17 A. I have specific recollection that  
18 that was one of the subjects that we're asked  
19 to consult upon. I don't have a specific  
20 recollection what device was involved.

21 Q. Do you have a specific recollection  
22 of what types of information were consulted or  
23 considered in that, in connection with that  
24 question?

25 A. From my angle, what I remember are

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2 questions relating to biomedical engineering  
3 in the clinical environment. So if I'm not  
4 mistaken, one of the devices was a cleaning  
5 and sterilizing equipment for proctoscopes,  
6 scopes that are used in the rectum, and how  
7 you clean it between uses. And this cleaner  
8 has a predicate device that said here is why  
9 we are substantially equivalent.

10 The question was relating to how in  
11 the real world, in a clinical environment,  
12 this other device is being used.

13 Q. Any other instance you can recall  
14 being asked to evaluate a substantial  
15 equivalence question?

16 A. No.

17 Q. Have you ever inspected a  
18 manufacturer on behalf of FDA?

19 A. No.

20 Q. Have you ever had any input into  
21 any FDA compliance decision?

22 A. No.

23 Q. Have you ever been consulted in any  
24 of these panels with respect to whether a  
25 device was adulterated or misbranded?

1 Y. DAVID

2 Q. In your professional capacity  
3 outside of litigation, have you ever had  
4 reason to review an inspection report from the  
5 agency?

6 A. Outside litigation, no.

7 Q. And have you ever consulted with  
8 FDA in the preparation of an Establishment  
9 Inspection Report?

10 A. No.

11 Q. You said that you have consulted  
12 with -- I'm sorry, let me just ask a better  
13 question.

14 Have you ever consulted with  
15 medical device companies about regulatory  
16 topics?

17 A. Yes.

18 Q. Are you able to identify any of the  
19 companies for me?

20 A. On page 2 of my CV under  
21 "Professional Experience," you have "Interim  
22 CEO, Canopy Edge." That's specifically  
23 involved with preparing the product for  
24 regulatory submission.

25 Q. What is that product?

1 Y. DAVID

2 A. It is a vascular catheter.

3 Q. Has a 510(k) -- I'm sorry. Will  
4 that be submitted as a 510(k) or a PMA, do you  
5 know?

6 A. It is still being reviewed.

7 Q. Any other medical device for which  
8 you've provided consulting on regulatory  
9 topics?

10 A. There are two other companies. One  
11 is called, I believe, Carmel Industries,  
12 C-A-R-M-E-L. And the other one is Begamed,  
13 B-E-G-A-M-E-D.

14 Q. What products?

15 A. Begamed.

16 Q. Were there specific products?

17 A. Begamed's product is laparoscopic  
18 suture, surgical instrument. And Carmel  
19 Industry is a software-based labor and  
20 delivery package.

21 Q. With respect to these three  
22 products that you've just identified, what is  
23 your role? What type of regulatory advice are  
24 you providing?

25 A. Wait a second. There is one more.

1 Y. DAVID

2 There is one more and I can't remember the  
3 name. But their product, this additional  
4 entity, their product is a brain stimulator.  
5 And let me answer your question about what  
6 they asked me to do. The brain stimulator was  
7 going to submit a 510(k) and wanted to know  
8 what are the electrical safety terms and  
9 conditions that their testing needed to  
10 demonstrate compliance with.

11 Q. Okay.

12 A. IEC 60601-1.

13 The Carmel Industry, they wanted to  
14 know if there is a predicate device to their  
15 product that they can use for substantial  
16 equivalency.

17 The Begamed wanted to understand if  
18 their product will be qualified for 510(k) if  
19 there are substantial equivalent predicate  
20 devices and if there is a requirement for  
21 animal testing.

22 Q. Are sutures what class?

23 A. Class 2.

24 Q. What about the software-based labor  
25 and delivery package?

1 Y. DAVID

2 A. I don't remember.

3 Q. Do you remember for the brain  
4 stimulator?

5 A. Class 2.

6 Q. And the vascular catheter is still  
7 under evaluation?

8 A. Correct.

9 Q. For the vascular catheter, what is  
10 the advice you're being asked about to  
11 provide?

12 A. What type of testing and  
13 information will be required for submission.

14 Whenever we can take a break...

15 Q. Pardon? Sure.

16 THE VIDEOGRAPHER: We are going off  
17 the record at 15:20.

18 (Recess, 3:20 p.m. to 3:32 p.m.)

19 THE VIDEOGRAPHER: We are back on  
20 the record at 15:32.

21 BY MS. EATON:

22 Q. Dr. David, have you ever designed a  
23 patient warming device?

24 A. No.

25 Q. Have you ever made or published any

1 Y. DAVID

2 presentation on Bair Hugger devices?

3 A. No.

4 Q. Before your work in this case, had  
5 you ever read any studies related to Bair  
6 Hugger devices?

7 A. No.

8 Q. At any time, have you performed  
9 testing related to Bair Hugger devices other  
10 than what we have discussed today?

11 A. No.

12 Q. At any time, have you performed  
13 research related to Bair Hugger devices that  
14 is not either reflected in your report or in  
15 what we have discussed today?

16 A. No.

17 Q. Have you undertaken any effort --  
18 sorry, let me ask that differently.

19 Before your work in this case, had  
20 you reviewed any hospital practices with  
21 respect to Bair Hugger devices?

22 A. A specific brand name Bair Hugger,  
23 no. But relating to patient warming, yes.

24 Q. What had you reviewed related to  
25 patient warming prior to your work in this

1 Y. DAVID

2 case?

3 A. Patient warming is a very important  
4 part of maintaining patient condition during  
5 disease management and following surgery or  
6 during trauma, so as part of my responsibility  
7 as director of biomedical engineering, for  
8 over 30 years I was involved in reviewing  
9 warming devices for adult and pediatric  
10 patients using either a literally oven-warmed  
11 blanket or devices that use fluids to warm  
12 patients or cool them or radiation-based  
13 devices that they are used in different  
14 environments.

15 The specific sensitivity that I  
16 became very familiar with the warming  
17 technology of patients is the one involving  
18 pediatrics, and we were having a very  
19 interesting project where we were trying to  
20 put warming devices in the emergency room, in  
21 the trauma center where the ambulances would  
22 bring babies, and determine how fast we can  
23 bring their body temperature up in those  
24 trauma situations.

25 And we were putting an infrared

1 Y. DAVID

2 warming device in the ceiling of the trauma  
3 center and making testing and examination of  
4 mannequin, small size, having ice cube on  
5 them, and determine the temperature change of  
6 the body. And this specific example that I  
7 became intimately familiar with the issue of  
8 maintaining or warming patients under trauma  
9 situations.

10 The other example that I would like  
11 to bring in front of you is the neonatology  
12 arena where premature babies are born and are  
13 not able to maintain their body temperature,  
14 not because of trauma or disease, just because  
15 of their stage in early life. And those  
16 babies are tremendously sensitive to body core  
17 temperatures and it's very difficult to warm  
18 them up without causing skin damage.

19 So infant warmers, Isolettes, those  
20 are warm air, forced warm air contraption  
21 boxes that you put babies in and need to have  
22 specific monitoring for the humidity and the  
23 temperature inside to make sure that the  
24 babies are not drying up and not being  
25 basically cooked.

1 Y. DAVID

2 And we did many studies and  
3 published several research papers on that, and  
4 I developed a protocol to -- how to test those  
5 devices later on in their life. So once we  
6 developed it, we learned how to use it and how  
7 to maintain and service it.

8 Q. Did you mean later on in the life  
9 of the device or --

10 A. Correct, yes. Thank you.

11 Q. That's what I thought in context as  
12 opposed to the life of the babies.

13 Did you do -- you meant the device?

14 A. Yes.

15 Q. Okay. Did any aspect of your  
16 testing or evaluation with respect to the  
17 Isolettes used for premature babies relate to  
18 contamination or infection risk?

19 A. It has that aspect and we have  
20 epidemiologists that were part of the study  
21 and that was their responsibility to collect  
22 the data and look at the statistics. So it  
23 was not something that I would do.

24 Q. Okay. Are you familiar with any of  
25 their determinations or the results of their

1 Y. DAVID

2 radiating panel were absorbing more heat than  
3 the patient him or herself. That was a  
4 drawback.

5 Q. Was a consideration of  
6 contamination or infection risk any part of  
7 the evaluation in that trauma setting?

8 A. Not in that study, no.

9 Q. Any other time in your work outside  
10 of litigation that you have been personally  
11 involved in evaluating patient warming?

12 A. Yes. The other example would be in  
13 the cardiovascular theater, cardiovascular  
14 operating room. I don't know, Counsel, if  
15 you're aware, but the St. Luke's Episcopal  
16 Hospital that I was involved with is the home  
17 of the Texas Heart Institute, which is the  
18 highest-volume heart surgery hospital --  
19 institution in the country, maybe in the  
20 world.

21 So they are having significant  
22 amount of large volume of heart surgery with  
23 patients that are being cooled down on  
24 purposely to slow the metabolism and  
25 blood-brain barrier.

1 Y. DAVID

2 Those patients are expected to be  
3 well monitored and controlled as far as where  
4 their core temperature is, and when they are  
5 being brought back, there should be a certain  
6 rate of core temperature rising that one  
7 should expect to see, no faster, no slower.  
8 You do that with what the CDC meeting was here  
9 about, fluid warming and cooling devices. And  
10 you circulate the blood through a cooler  
11 element or a heating element, and these  
12 heating or cooling elements are devices that I  
13 was responsible for and participated in the  
14 study.

15 We published a couple of studies on  
16 those -- I don't think that they are on my  
17 CV -- at the Texas Heart Institute Journal  
18 about the temperature control devices for  
19 postcardiac surgery, and I think there is one  
20 study that is in my list that is looking at  
21 outcome of patient that underwent cardiac  
22 surgery and their scalp temperature did not  
23 rise fast enough to predict their outcome.

24 Q. Did any of the studies that you  
25 took part in or the publications have anything

1 Y. DAVID

2 Medical Center and, again, the cardiovascular  
3 program was at the time developed and I worked  
4 with Dr. Tarnay, who was a cardiovascular  
5 surgeon, about cooling and warming patients  
6 with particular devices at the time.

7 But I don't believe that my  
8 involvement was in the area of infections or  
9 infection prevention.

10 Q. Do you recall any discussion, in  
11 any of your work outside of litigation, where  
12 a hospital was considering removing devices  
13 from the operating room because of air blowing  
14 from the devices?

15 A. Not exactly what you are asking,  
16 but I was involved in reviewing and evaluating  
17 operating room pollutions from  
18 anesthesia-based gases that are expelled from  
19 a patient after they breathe it. And the  
20 records are suggesting that a minute amount of  
21 those gases, if exposed by operating room  
22 staff, that person, people, would lead to  
23 miscarriages and other undesirable outcome.

24 So I was involved in study to  
25 monitor the influence of air exchanges in the

1 Y. DAVID

2 surgical theater and the amount of gas coming  
3 from the end of the anesthesia machine when  
4 mannequins were connected with simulated lungs  
5 to them. That probably is as close as I can  
6 come to your question.

7 Q. Have you ever been involved in  
8 designing a cleaning protocol for an operating  
9 room or for the equipment in it?

10 A. There is equipment that is being  
11 circulated through the operating room, not  
12 necessarily you would call it operating room  
13 fixed equipment, but the specific example I  
14 have in mind for you is infusion pump, and  
15 drug administration medical devices such as  
16 infusion pump are probably in the thousands in  
17 quantity in hospitals around the country and  
18 they are being used in the emergency room, on  
19 the general floor, in the operating room, and  
20 they are circulating through various  
21 environments.

22 I was involved with the central  
23 processing supply team that looked at means to  
24 clean and disinfect those pumps once they come  
25 out of the patient arena, areas. And that's

1 Y. DAVID

2 were selected, do you recall?

3 A. No, I don't recall because they  
4 have brand name, germicide -- germicide or --  
5 they have a specific brand name at the time  
6 that were picked up, and I don't remember.

7 Q. And do you remember what the  
8 chemicals were, separate from the brand names?

9 A. Those were agents that were -- that  
10 are able to penetrate biofilm and kill  
11 bacteria. I don't remember the names.

12 Q. Were these agents for use on the  
13 outside of medical equipment or on the inside  
14 of medical equipment?

15 A. By a majority, they were on the  
16 outside. However, some equipment like the  
17 warming/cooling circulating device in  
18 cardiovascular operating room has tanks that  
19 you have accessibility to the inside of their  
20 container, so it was used inside as well.

21 Q. Were you part of determining the  
22 cleaning protocol for the heater/cooler units?

23 A. I was part of the team. I wouldn't  
24 say that I determined how it should be done,  
25 but I was part of the team and my expertise

1 Y. DAVID

2 came from the biomedical engineering, for  
3 example, to make sure that the agent is not  
4 damaging the equipment.

5 Q. With respect to hoses used in  
6 operating rooms, that would be an important  
7 consideration, right? Not damaging the  
8 equipment with the cleaning agent?

9 A. Right.

10 Q. Were you involved in determining  
11 the interval of cleaning for any of the  
12 equipment you've identified?

13 A. I would bring my recommendation  
14 after I consulted with the manufacturers on  
15 that, so we will present specific scenario.  
16 That's how many patients a day we expect this  
17 device to be used on, these are the agents we  
18 would like to use, and this is the process we  
19 will use them. And I would expect the  
20 manufacturer to tell me what will be the  
21 impact on the device.

22 Q. So once the team you were working  
23 on -- let me just make sure I understood that.  
24 The team you were working with would determine  
25 what they would wish to do and then consult

1 Y. DAVID

2 developed in connection with this case?

3 A. I believe that I described several  
4 times today that it's been much beyond that.  
5 In the areas of operating room design, cardiac  
6 catheterization room design, I was involved  
7 with probably 50 or 60 of those facilities and  
8 equipment planning and discussion about  
9 filtration and filters were part of the team  
10 discussion.

11 I did not select filters, as I said  
12 before, but that's where my working knowledge  
13 comes from.

14 Q. Have you ever conducted testing of  
15 a filter, any kind of testing of a filter?

16 A. I don't believe that I did.

17 Q. Have any of your work  
18 responsibilities outside of litigation  
19 involved filtration on medical devices  
20 specifically as opposed to rooms?

21 A. The examples that come to my mind  
22 as we sit here today are involvements that I  
23 have with mechanical ventilators and bedside  
24 monitors. Those two product categories  
25 involve both protection of the device from

1 Y. DAVID

2 penetration of bacteria from the outside as  
3 well as protection of the device from  
4 developing pathogens in the internal cavities.

5 Q. In what context have you worked  
6 with those two devices?

7 A. With the ventilators, I was invited  
8 to travel to Travemünde in Germany. That's  
9 where Dräger Medical is located and doing  
10 their research and manufacturing, and they  
11 were developing a new pediatric ventilator and  
12 wanted to have an opinion about how the  
13 clinicians and the biomedical engineers and  
14 the hospital will review their product  
15 features.

16 So they took the medical director  
17 of the neonatology ICU, a respiratory  
18 therapist director and myself, and we were  
19 participating in brainstorming session that  
20 looked at how the device is going to be  
21 maintained, its cleanliness, in face of some  
22 challenging environment, challenging in regard  
23 to pathogens.

24 The other example involved bedside  
25 monitoring, and on that product I was invited

1 Y. DAVID

2 A. In the McGovern study, they have  
3 the Bair Hugger and when they removed it and  
4 used another patient warming device, there was  
5 81% reduction in infection. With the Bair  
6 Hugger, there was 3.8 index increased  
7 probability of infection.

8 At the incident with the literature  
9 review that I cited in my report, looking at  
10 all the studies, the conclusion was simple  
11 that a HEPA filter is one of the ways to  
12 mitigate infection. The CDC article that I  
13 have in my publication also talks about  
14 filtering level efficiency. They -- the  
15 literature from orthopedics, Bone & Joint  
16 Journal, is talking about one of the solution  
17 is increase filter efficiency.

18 So there's ample evidence out there  
19 that there is a relationship between filter  
20 efficiency and the potential risk of infection  
21 at the surgical site.

22 BY MS. EATON:

23 Q. Would a 75% capture of .2-micron  
24 particles change the clinical risk as opposed  
25 to a 90% capture of .2-micron particles?

1 Y. DAVID

2 infection and it did not.

3 A. I don't think so.

4 Q. Did you locate any articles that  
5 concluded specifically that the Bair Hugger  
6 device decreased the risk of surgical site  
7 infection?

8 (Document review by witness.)

9 A. One of the articles that I indicate  
10 and consider is the review article of existing  
11 literature by Wood, Moss and Keenan, and I'm  
12 not sure, I need to read the study again, but  
13 maybe one of the articles there was saying  
14 there was no difference. I don't think that  
15 there was decrease, but no difference. I just  
16 need to read that paper again.

17 BY MS. EATON:

18 Q. If there were articles that  
19 established that the -- I'm sorry. If there  
20 were articles that reported that the use of a  
21 forced-air warming device during surgery  
22 decreased the risk of surgical site infection,  
23 would that be relevant to your consideration?

24 A. It would.

25 Q. If there were articles

1 Y. DAVID

2 BY MS. EATON:

3 Q. Will contribute a higher risk than  
4 if it were not used?

5 A. Correct.

6 Q. Is the interpretation of clinical  
7 study data about infection risk something that  
8 you have ever done outside of your work in a  
9 lawsuit?

10 A. Can you ask it again?

11 Q. Outside of your work for a lawsuit,  
12 is the interpretation of clinical study data  
13 concerning infection risk something that you  
14 do?

15 A. In my work, I'm expected to read  
16 clinical literature and scientific  
17 publication. I am educated, trained, and have  
18 the experience to understand the study  
19 structure and the strength of the conclusions.

20 And in my evaluation of various  
21 medical devices, at the hospital I worked for  
22 for over 25, 30 years, part of the process was  
23 to review current medical and scientific  
24 literature relating to device performance and  
25 bring that to what in my report describe as

1 Y. DAVID

2 MTEC, M-T-E-C, Medical Technology Evaluation  
3 Committee, that looked at the overall what you  
4 asked earlier, benefit-to-risk ratios and  
5 understand what the product risk based on the  
6 information from the manufacturers, but also  
7 based on experience that comes from clinical  
8 studies that published in peer-reviewed  
9 journals.

10 Q. If the use of a forced-air warming  
11 device decreases infection risk, would that be  
12 relevant to a clinical benefit-risk  
13 assessment?

14 A. Yes.

15 Q. Okay. In your work -- well, you --  
16 have you ever -- more probable than not, is  
17 that a scientific standard?

18 A. Yes.

19 Q. Okay. Is there anyplace in an  
20 engineering standard that you say more  
21 probable than not is the criteria?

22 A. Many times.

23 Q. Can you identify one?

24 A. Can I make a joke in a casino?

25 Yes. For example, when the Space

1 Y. DAVID

2 supplement the product that they have. And  
3 when you do not have warm air circulating but  
4 it's a closed loop, I don't think that you  
5 need to be an expert to realize that you're  
6 removing a threat. You therefore are reducing  
7 exposure to the risk.

8 Q. Are you familiar with the concept  
9 that direct contact with a surface can pose an  
10 infection risk?

11 A. That makes sense.

12 Q. Is that something that you're  
13 familiar with in your work in the hospitals?

14 A. Well, hand hygiene is a typical  
15 example. Very, very known in hospitals.

16 Q. And reusable medical equipment that  
17 directly touches patients, that's also an  
18 example?

19 A. Well, it's not the same because  
20 most of the accessories that will touch  
21 patients will be disposable, single use, and  
22 probably sterile. So that's not the same as  
23 hands touching surfaces.

24 Q. Have you provided in your report  
25 all of the data that you reviewed with respect

1 Y. DAVID

2 to the alternative products that you've  
3 identified?

4 A. Yes, I did.

5 MS. EATON: Do I have any time  
6 left?

7 THE REPORTER: You're at 6:48.

8 MS. EATON: Okay. I'm going to  
9 reserve.

10 MR. BANKSTON: Yeah, I'm a little  
11 hot so we'll take a literally two- or  
12 three-minute break.

13 THE VIDEOGRAPHER: We're going off  
14 the record at 18:08.

15 (Recess, 6:08 p.m. to 6:17 p.m.)

16 THE VIDEOGRAPHER: We are back on  
17 the record at 18:17.

18 EXAMINATION

19 BY MR. BANKSTON:

20 Q. Dr. David, you were asked some  
21 questions about risk-benefit. Do you remember  
22 those questions?

23 A. I do.

24 Q. Okay. First of all, is it your  
25 opinion that the Bair Hugger should be taken

1 Y. DAVID

2 out of rooms and not replaced with any form of  
3 patient warming?

4 A. No.

5 Q. Okay. Are there other devices  
6 available, other design concepts which are  
7 feasible to be made without the same risk  
8 mechanism that you identified in your report?

9 MS. EATON: Object to the form of  
10 the question.

11 A. Right. I indicated in my report  
12 and so is my opinion that I identify specific  
13 product with different features that remove  
14 the risk introduced by the Bair Hugger 750 and  
15 yet serve the purpose of controlling patient  
16 temperature environment.

17 BY MR. BANKSTON:

18 Q. Does the literature you reviewed  
19 contain any studies or any opinions concerning  
20 whether any of these devices are similar in  
21 effectiveness to the Bair Hugger at  
22 maintaining patient temperature?

23 A. I was trying to scan in my memory  
24 where that might be in my report.

25 Q. Let me know.

1 Y. DAVID

2 supportive is that resistant heating  
3 mattresses are of equal efficiency to the Bair  
4 Hugger forced-air blanket in maintaining  
5 temperature, and that's why I incorporate that  
6 study here.

7 Q. Okay. From your engineering  
8 background and experience, do you have any  
9 opinion on whether, apart from these four  
10 devices, just from an engineering concept  
11 standpoint, is it possible, more likely than  
12 not, to design a device that does not pose the  
13 risks you've identified but warms patients as  
14 effectively?

15 MS. EATON: Object to the form of  
16 the question.

17 A. These devices that I show as  
18 alternatives are demonstrating that. 3M  
19 engineers have several concepts that they came  
20 up with. One of them is the, I believe,  
21 recirculating, is basically what I have in my  
22 alternative design, so it is feasible.

23 BY MR. BANKSTON:

24 Q. Okay. You were asked some  
25 questions about speaking to hospitals about

1 Y. DAVID

2 infection, and there's no correlation between  
3 colorectal procedures and orthopedic surgical  
4 procedure.

5 BY MR. BANKSTON:

6 Q. Okay. There was some testimony  
7 today about the literature review conducted by  
8 Dr. Wood and his associates. Do you know  
9 which study I'm referring to there?

10 A. Yes.

11 Q. Okay. In that review, was there  
12 information -- did it simply include studies  
13 that were unfavorable to the Bair Hugger or  
14 did it also include some studies that claimed  
15 to be favorable to the Bair Hugger?

16 MS. EATON: Objection to the form.

17 A. As I sit here today, I don't  
18 remember all the studies. There are probably  
19 15. He looked at what's available in the  
20 literature at the time he conducted his study,  
21 but those are the -- representative of the  
22 knowledge that was in the field at that time.

23 BY MR. BANKSTON:

24 Q. Okay. You're familiar -- we've  
25 discussed much today -- there are multiple

1 Y. DAVID

2 models of the Bair Hugger?

3 A. Yes.

4 Q. Okay. If there are articles out  
5 there discussing bacterial sampling with a  
6 previous model 500 series instead of a model  
7 700 series, can you tell me if or if not that  
8 would have any direct engineering application  
9 to your opinions about the model 700 series in  
10 this case?

11 MS. EATON: Objection to the form.

12 A. It's very important because the  
13 features of those two families of product, the  
14 750 and the 500, are different from  
15 engineering perspectives in that the filter  
16 characteristic is different and the volume of  
17 flow air pushed through them is also greatly  
18 different.

19 BY MR. BANKSTON:

20 Q. Dr. David, can you pull out your  
21 report for me and flip to page 20?

22 A. I'm there.

23 Q. Do you see at the top references to  
24 some scientific work by Hall and by Zink?

25 A. Yes, I do.

1 Y. DAVID

2 Q. Are you familiar with what these  
3 studies are?

4 A. Yes.

5 Q. Okay. Can you briefly explain what  
6 the context of these studies are?

7 A. Yes. I read those articles. Hall  
8 is talking about, I believe, eight volunteers  
9 that were subjected to a culture count, and  
10 Zink is talking about, I believe, 16 patients  
11 that were in a completely different  
12 environment than orthopedics procedure.

13 Q. Dr. David, can you tell -- can you  
14 tell the jury generally what your impression  
15 of your task in this case was?

16 A. Absolutely. And I actually put it  
17 as the first paragraph in my report, that my  
18 task was to review the hazards and risk  
19 associated with the Bair Hugger 750 family and  
20 to opine about if that would contribute to  
21 unreasonable dangerous biomedical engineering  
22 device that increase the probability of  
23 infection in orthopedics procedure or not.

24 Q. Okay. Can you tell me a little  
25 bit -- no, let me take that back. In coming

1 Y. DAVID

2 supplies.

3 So the committee was representing  
4 so many expertise and I was in the position  
5 where I had to receive their input and derive  
6 recommendation to the hospital management if a  
7 device is beneficial with lower risk than what  
8 is being used today or until that product  
9 come.

10 So I believe that I have the  
11 qualification based on academic training and  
12 experience working with these stakeholders and  
13 with this group to specifically evaluate and  
14 assess risk-benefit ratios.

15 Q. Do you feel like you have enough  
16 materials to give yourself an informed and  
17 helpful opinion that you can communicate to  
18 the jury?

19 A. I do. And when I felt that I don't  
20 have enough material, I approached you,  
21 Counsel, and requested specific documents or  
22 information. So I'm comfortable that I  
23 received the material that I need to arrive at  
24 the opinions.

25 Q. And do you feel confident today

1 Y. DAVID

2 A. I'm trying to understand your  
3 question. Prohibition on published  
4 hospital...

5 Q. If you had an interpretation of  
6 published literature about a forced-air  
7 warming device or any other device, would you  
8 be free to talk to a hospital about that?

9 A. During this litigation, I don't  
10 feel so.

11 Q. You simply can't speak at all about  
12 patient warming devices, to your  
13 interpretation?

14 MR. BANKSTON: Object to the form.

15 A. As it relates to the condition of  
16 this litigation, yes, that's the way I feel.

17 BY MS. EATON:

18 Q. Okay. Did you review an ECRI  
19 evaluation of the potential risk of infection  
20 with Bair Hugger use?

21 A. Yes.

22 Q. Did you cite that in your report?

23 A. Good question. I don't think so.

24 Q. Do you believe you reviewed it  
25 before you wrote your report or after?

1 Y. DAVID

2 A. After.

3 Q. Okay. Do you believe you reviewed  
4 it -- can you tell me when you reviewed it?

5 A. I became aware that they made a  
6 report and wanted to understand what they  
7 considered, so I would say probably in the  
8 last month or so.

9 Q. Are there any other materials  
10 related to this case that you reviewed in the  
11 last month that we haven't discussed here  
12 today and have not been identified for me  
13 today?

14 A. No.

15 Q. Okay. Did you agree with the  
16 conclusion of ECRI?

17 A. I believe they attempted to  
18 understand the condition. They're operating  
19 in a different environment than I am, and they  
20 concluded that what I believe is that  
21 additional studies are needed.

22 Q. They concluded that there was not  
23 sufficient evidence to determine that there  
24 was an increased risk with the Bair Hugger  
25 device, right?

1 Y. DAVID

2 MR. BANKSTON: Object to the form.

3 A. The way I understand their document  
4 or what I read is that they have not find  
5 material to recommend the discontinued use of  
6 the Bair Hugger and that additional studies  
7 are required to better address that issue.

8 BY MS. EATON:

9 Q. Did you disagree with anything  
10 about the method they used to identify  
11 information they reviewed?

12 A. No.

13 Q. Did they use a more comprehensive  
14 method than you used to identify literature?

15 A. Counsel, they are doing different  
16 things than I'm doing. I think that I  
17 mentioned that this is a different  
18 environment. They have a relationship with  
19 industry, with hospital as customers, and  
20 they're looking at an overall.

21 I have specific charge to my work.  
22 I'm not studying the complete concept of what  
23 is patient warming is all about. I have  
24 specifically charge as mentioned in the  
25 opening of my report.